

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN,
LOSARTAN, AND IRBESARTAN
PRODUCTS LIABILITY
LITIGATION

MDL No. 2875

THIS DOCUMENT RELATES TO ALL
CASES

HON. ROBERT B. KUGLER
MDL NO. 19-2875 (RBK)

**CERTIFICATION OF ADAM M. SLATER IN
SUPPORT OF PLAINTIFFS' *DAUBERT* MOTION TO PRECLUDE
THE OPINIONS OF DEFENSE EXPERT FENGTIAN XUE, PH.D.**

ADAM M. SLATER, hereby certify as follows:

1. I am an attorney at law within the State of New Jersey and a partner with the law firm of Mazie Slater Katz & Freeman, LLC, and serve as Plaintiffs' Co-Lead Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' motion to exclude the testimony of Defense Expert Fengtian Xue, Ph.D.
2. Attached hereto as **Exhibit 1** is a true and accurate copy of Fengtian Xue's PSC Faculty Profile.
3. Attached hereto as **Exhibit 2** is a true and accurate copy of Fengtian Xue's Report, dated December 22, 2022 in this case.
4. Attached hereto as **Exhibit 3** is a true and accurate copy of the transcript of Fengtian Xue's February 3, 2023 deposition in this case.
5. Attached hereto as **Exhibit 4** is a true and accurate copy of ZHP's Investigation Regarding Unknown Impurity (Genotoxic Impurity) of Valsartan API (Version 2) (PRINSTON00075797).

6. Attached hereto as **Exhibit 5** is a true and accurate copy of ZHP's Investigation Regarding Unknown Impurity (Genotoxic Impurity) of Valsartan API (Version 3) (PRINSTON0076100).

7. Attached hereto as **Exhibit 6** is a true and accurate copy of the relevant excerpts of ZHP's April 14, 2019 Correspondence with the FDA (PRINSTON00158423).

8. Attached hereto as **Exhibit 7** is a true and accurate copy of Sun, Liu, and Zhong, *Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Trimethylamine*, J. Phys. Chem. A. 114, 455-465 (2010).

9. Attached hereto as **Exhibit 8** is a true and accurate copy of Gowenlock, Hutchinson, Little, Pfab, *Nitrosative dealkylation of some symmetrical tertiary amines*, J. Chem. Soc., Perkin Trans. 2, 1110-1114 (1979)

10. Attached hereto as **Exhibit 9** is a true and accurate copy of *Player v. Motiva Enterprises LLC*, No. Civ. 02-3216(RBK), 2006 WL 166452 (D.N.J. Jan. 20, 2006).

11. Attached hereto as **Exhibit 10** is a true and accurate copy of FDA, Guidance for Industry, *Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches* (Dec. 2008)

12. Attached hereto as **Exhibit 11** is a true and accurate copy of ZHP's ZnCl₂ DMF, Impurities Section (HUAHAL-US00007752).

13. Attached hereto as **Exhibit 12** is a true and accurate copy of ZHP's TEA with Sodium Nitrite Quenching DMF, Impurities Section (PRINSTON00080011).

14. Attached hereto as **Exhibit 13** is a true and accurate copy of the transcript of Peng Dong's March 29, 2021 deposition in this case.

15. Attached hereto as **Exhibit 14** is a true and accurate copy of Long & Meek, *Concise International Chemical Assessment Document 31: N,N-Dimethylformamide* (WHO 2001).

16. Attached hereto as **Exhibit 15** is a true and accurate copy of Shandong Hualu-Hengsheng Chem Co., *Certification of Analysis for N,N-Dimethylformamide*.

17. Attached hereto as **Exhibit 16** is a true and accurate copy of Fengtian Xue's Amended and Supplemental List of Materials Reviewed and Considered.

18. Attached hereto as **Exhibit 17** is a true and accurate copy of Zhejiang Jianye Chemical Co., Ltd.'s Certificate of Analysis for Triethylamine.

19. Attached hereto as **Exhibit 18** is a true and accurate copy of Juillard, *Dimethylformamide: Purification, Tests For Purity And Physical Properties*, Int'l Union of Pure and Applied Chem (Pergamon Press 1977).

20. Attached hereto as **Exhibit 19** is a true and accurate copy of the transcript of Min Li's April 20, 2021 deposition in this case.

21. Attached hereto as **Exhibit 20** is a true and accurate copy of Plaintiffs' translation of Jinsheng Lin's July 27, 2017 email regarding the NDMA contamination of ZHP's valsartan (ZHP00190573).

22. Attached hereto as **Exhibit 21** is a true and accurate copy of ZHP's translation of Jinsheng Lin's July 27, 2017 email regarding the NDMA contamination of ZHP's valsartan (ZHP00190573).

23. Attached hereto as **Exhibit 22** is a true and accurate copy of the transcript of Min Li's April 22, 2021 deposition in this case.

24. Attached hereto as **Exhibit 23** is a true and accurate copy of Fengtian Xue's Supplemental Report, dated January 30, 203, in this case.

25. Attached hereto as **Exhibit 24** is a true and accurate copy of Dr. Stephen S. Hecht's July 6, 2021 expert report in this case.

26. Attached hereto as **Exhibit 25** is a true and accurate copy of the transcript of Jun Du's May 28, 2021 deposition in this case.

27. Attached hereto as **Exhibit 26** is a true and accurate copy of Dr. Stephen S. Hecht's October 31, 2022 expert report in this case.

MAZIE SLATER KATZ & FREEMAN, LLC
Attorneys for Plaintiffs

By: /s/ Adam M. Slater

Dated: May 13, 2022